

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/823,868	DINELLO ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Bao-Thuy L. Nguyen	1641	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to After final Amendment filed on 2/9/04.
2. ☒ The allowed claim(s) is/are 28-31, 36-39 and 42-45 which have been renumbered.
3. ☒ The drawings filed on 30 March 2001 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |   |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)  | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                       |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                               |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material          | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance              |
|   | 9. <input type="checkbox"/> Other _____.  |

Bao-Thuy L. Nguyen  
Primary Examiner  
Art Unit: 1641

### EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.
2. Authorization for this examiner's amendment was given in a telephone interview with Roberta Robins on March 15, 2004.

The application has been amended as follows:

In the claims:

28. (Twice amended) A method for detecting an analyte in a sample comprising:  
delivering a buffer to a test strip to prewet the test strip, wherein said test strip comprises (i) a buffer addition zone, (ii) a sample addition zone, (iii) one or more test zones positioned between the buffer addition zone and the sample addition zone wherein at least one of the test zones includes a first analyte binding agent immobilized therein which binds to analyte in the sample, and (iv) a terminal buffer flow zone positioned between the one or more test zones and the sample addition zone, and (v) an absorbent zone positioned relative to the buffer addition zone [and with] having absorbent properties such that when a predetermined volume of buffer is added to the [test strip] buffer addition zone, the buffer diffuses through the one or more test zones into the terminal buffer flow zone and the absorbent properties of the absorbent zone cause the buffer to be drawn backward across the test zones toward the buffer addition zone and into the absorbent zone [(a) diffuses to the one or more test zones, (b) diffuses

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to the terminal buffer flow zone, changes direction and (c) diffuses past the one or more test zones and past the buffer addition zone into the absorbent zone];

delivering a sample to the sample addition zone of the test strip, delivery of the sample [causing] causes analyte in the sample to diffuse past the terminal buffer flow zone to the one or more test zones and to the absorbent zone, after the buffer diffuses past the one or more test zones, the analyte binding to the first analyte binding agent and becoming immobilized in the test zones; and

detecting the analyte immobilized in the test zones.

29. (amended) A method according to claim 28 wherein the method further comprises

detecting a second analyte [binding agent] and the test strip further includes a second analyte binding agent which [is capable of binding] specifically binds to the analyte, wherein said second analyte binding agent is positioned in the sample addition zone or in a zone between the sample addition zone and the terminal buffer flow zone, [addition of the sample causing the second analyte binding agent to bind to analyte in the sample, binding of the analyte to the first analyte binding agent causing the second analyte binding agent to be immobilized in the test zones, and]

adding a sample to the sample additional zone thereby causing the second analyte binding agent to bind to analyte in the sample, capturing the complex comprising the analyte and the second analyte binding agent in the one or more test zone by binding of the complex to the immobilized first binding agent in the test zone;

detecting the analyte immobilized in the test zones by [comprising] detecting the second analyte binding agent.

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3. The following is an examiner's statement of reasons for allowance: the claims are free of the prior art because the prior art fails to teach a method using a device having various reagent zones and specifically an absorbent zone having absorbent properties such that when a predetermined volume of buffer is added to a buffer addition zone, the buffer diffuses through one or more test zones into a terminal buffer flow zone, and the absorbent properties of the absorbent zone cause the buffer to be drawn backward across the test zones toward the buffer addition zone and into the absorbent zone.

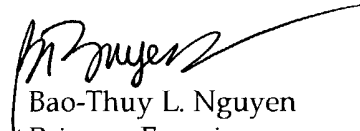
Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Thursday from 9:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Bao-Thuy L. Nguyen  
Primary Examiner  
Art Unit 1641